

AMENDMENTS TO THE SPECIFICATION

At page 1 immediately below the title, please replace the first paragraph of the specification, which was inserted in the Preliminary Amendment filed February 11, 2002, with the following paragraph:

--This is application is a divisional of U.S. Application Serial No. 09/581,897, filed October 2, 2000, now U.S. Patent No. 6,369,220, which is a 35 U.S.C. § 371 national stage application of International Application PCT/US98/26216, filed December 16, 1998, which claims the benefit of priority of U.S. Provisional Application Serial No. 60/068,170, filed December 19, 1997. The entire contents of each is herein incorporated by reference. --

REMARKS/ARGUMENTS

The first paragraph of the specification has been amended to (1) include the patent number of the now-issued parent patent, of which the present application is a continuation, and (2) clarify the priority of the present application.

Claims 1, 65, and 66 are pending in the application.

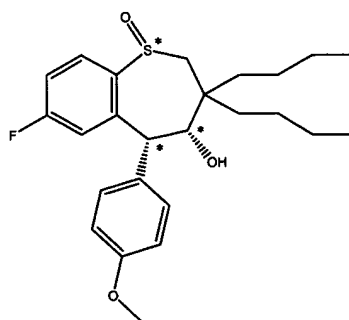
**Restriction Requirement under 35 U.S.C. §121 and Election of Species**

*i) Election*

The Office Action has imposed a restriction requirement among seven groups. This restriction acknowledges that compounds of formula (I), when divided along the lines of Groups I-VII, are separately patentable inventions. *See* MPEP § 806.04(h).

Applicants hereby elect, with traverse, the invention of Group I drawn to a method of preparing an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide of formula (I) wherein R<sup>1</sup> and R<sup>2</sup> are H, alkyl, alkenyl, or alkynyl; R<sup>3</sup> is H, alkyl, alkenyl, alkynyl, aryl, or cycloalkyl wherein aryl can be substituted with alkyl, alkenyl, alkynyl, polyalkyl or OR<sup>19</sup> wherein R<sup>19</sup> is H, alkyl, alkenyl, alkynyl, or polyalkyl; and R<sup>4</sup>-R<sup>7</sup> are H, alkyl, alkenyl, alkynyl, or halo.

Applicants also hereby affirm the provisional election, made by Applicants' undersigned representative, of the species of Example 7 at page 46 of the specification. This species has the structure,



((4R, 5R) -XXIV)

\* = chiral center

and is a compound of the formula (I) of claim 1, wherein R<sup>1</sup> and R<sup>2</sup> are alkyl (n-butyl); R<sup>3</sup> is aryl (benzyl) substituted with OR<sup>19</sup>, wherein R<sup>19</sup> is alkyl (methyl); R<sup>4</sup>, R<sup>6</sup>, and R<sup>7</sup> are H; and R<sup>5</sup> is halo (fluoro).

ii) Arguments Traversing the Restriction Requirement

Page 6 of the Office Action contends, "Each group is independent or distinct and [is] capable of preparation by more than one process (as note[d] in the instant specification). Separate search considerations are involved. Moreover, not to restrict, the claims would impose a substantial burden on the examination of the application. "

Applicants respectfully submit that whether the claimed compounds can be prepared by one or more than one process has absolutely no bearing on whether restriction among Markush group members is proper. Moreover, the Office Action's claims of (1) separate search considerations and (2) a substantial burden on the Patent Office are negated by all seven of the divided being commonly classified in class 549. Instead, the unstated rationale for the restriction requirement appears to be the variety of moieties pendant from the core of the claimed

compound of formula (I). However, this alone cannot afford basis for requiring restriction.

Applicants further submit that the Office Action's approach is procedurally in direct contrast to well-established examination principles set forth MPEP § 803.02, relating to restriction practice for Markush claims. In particular, now that Applicants have complied with the election-of-species requirement, claim 1 must be fully examined on the merits. According to the above-cited MPEP section, in Markush claim practice,

...the examiner may require a provisional election of a single species prior to examination on the merits. ...Following election, the Markush-type claim will be examined fully with respect to the elected species and further to the extent necessary to determine patentability. (emphasis added).

In addition to its procedural inconsistency with the MPEP, the imposed restriction requirement additionally ignores the substantive considerations for Markush claim practice, as provided further in MPEP § 803.02. Specifically, this section states

If the members of the Markush group are ...so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. (emphasis added).

In claim 1, the members of the Markush groups are so closely related that a search and examination of the claims can be made without serious burden, because the Office Action acknowledges that all proposed restriction groups may be classified in class 549. Therefore, even assuming, *arguendo*, that claim 1 encompasses several independent and distinct inventions, there is still no basis for imposing a restriction.

Furthermore, MPEP § 803.02 states, "[I]t is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention." (emphasis added). Unity of invention is based on well-settled judicial precedent. For example, the MPEP cites *In re Harnisch* and *Ex parte Hozumi*. 206 U.S.P.Q. 300 (C.C.P.A.

1980) and 3 U.S.P.Q.2d 1059 (Bd. Pat. App. & Int. 1984). In *Harnisch*, the Court of Customs and Patent Appeals rejected the imposition of a restriction requirement in a Markush-type claim where all of the compounds had a single use, and thus had unity of invention. Likewise, in *Hozumi*, the Board of Patent Appeals and Interferences (hereinafter “Board”) reversed a rejection of a Markush-type claim, where the compounds were core structures having plural diverse pendant moieties.

Other decisions reinforce the proposition that unity of invention is based on a common utility. For example, in *In re Jones*, the Court of Customs and Patent Appeals reversed the Board’s ‘improper Markush group’ rejection precisely because the claimed compounds had a common function. 162 F.2d 479, 74 U.S.P.Q. 149 (C.C.P.A.1947). In *Ex parte Dahlen*, 42 U.S.P.Q. 208 (Bd. App. 1938), the Board permitted claims to compounds having a common core with pendant widely-varying side chains, because the claimed compounds had a community of properties.

Based on the above decisions, claim 1 has unity of invention, because claim 1 embraces a single inventive concept. The compounds prepared by the method of claim 1 are ileal bile acid transport-inhibiting compounds. The compounds of claim 1 have a single core and pendant moieties, as set forth in the definitions of R<sup>1</sup>-R<sup>7</sup>. No matter which combination of pendant moieties is selected, the resulting compound is an ileal bile acid transport-inhibiting compound. Such compounds may also have other uses, but all are ileal bile acid transport-inhibiting compounds. To restrict claim 1 to any scope less than its full scope is contrary to established precedent and MPEP guidance.

In summary, the splitting of the Markush groups of claim 1 according to the imposed restriction requirement is improper because, even if claim 1 contains independent and distinct

inventions, (1) no serious burden will result from a search the entire claim 1, (2) procedurally, examination of the entire claim 1 must follow an election of species, (3) substantively, examination of the entire claim 1 is required because unity of invention (*i.e.*, a common utility) exists in the claimed subject matter. For all of these reasons, claim 1 should be examined in its entirety. Withdrawal of the restriction requirement is respectfully requested.

If the restriction requirement is maintained, Applicants request clarification of the Group V-VII definitions, as they misconstrue the claimed subject matter. For example, Group VI is drawn to compounds wherein  $R^1$ ,  $R^2$ , and  $R^3$  are selected from the moieties  $P(O)R^{19}R^{20}$ ,  $P^+R^{19}R^{20}R^{21}A^-$ , etc. However, the claimed invention is directed to compounds wherein  $R^1$ ,  $R^2$ , and  $R^3$  are alkyl, alkenyl, alkynyl, aryl, cycloalkyl, heterocycle, quaternary heterocycle, and quaternary heteroaryl that can be substituted with these moieties. Groups V and VII share similar problems.

Furthermore, if the restriction requirement is maintained, Applicants also request “independent or distinct” invention groups encompassing the entire claimed subject matter. For example, none of the currently identified groups includes the claimed species wherein  $R^1$  and  $R^2$  are H, alkyl, alkenyl, alkynyl, or cycloalkyl and  $R^4$ - $R^7$  are cycloalkyl, aryl, heteroaryl, alkoxy, aryloxy,  $-NO_2$  or  $-NR^9R^{10}$ , as defined in claim 1. Many other arbitrary groups are apparently possible.

### **The Rejection of Claims 1, 65, and 66 under 35 U.S.C. § 102(e)**

Claims 1, 65, and 66 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Lee *et al.* (U.S. Patent No. 5,994,391; hereinafter “Lee”) for the reasons noted at page 8 of the Office Action. Applicants respectfully traverse this rejection.

For a later application to be entitled to the benefit of the date of an earlier, copending application, the earlier application must contain a disclosure of the invention claimed in the later application that complies with the written description requirement of 35 U.S.C. § 112. *Wagoner v. Barger*, 175 USPQ 85 (CCPA 1972). In the present application, the anticipation rejection is based on subject matter disclosed in Lee in Example 1402 at columns 293-298, pertaining to the preparation of an enantiomerically-enriched tetrahydrobenzothiepine-1-oxide compound. The Office Action asserts that Lee constitutes prior art under 35 U.S.C. § 102(e) based on an earlier effective filing date. Specifically, Lee claims priority to U.S. Applications 08/517,051; 08/305,526; and 60/013,119, all of which were filed before the December 19, 1997 priority date of the present application.

However, none of these prior-filed applications contains the subject matter of Example 1402. In fact, none of these applications discloses tetrahydrobenzothiepine-1-oxide compounds that are enantiomerically-enriched. The earliest related application disclosing this subject matter, upon which the Office Action relies for the 35 U.S.C. § 102(e) rejection, is U.S. Application 60/068,170, filed December 19, 1997, to which both Lee and the present application claim priority. Therefore, with respect to the subject matter of claims 1, 65, and 66, Lee is not entitled an earlier priority date, but rather the same priority date. Lee is not prior art under 35 U.S.C. § 102(e), because Lee's invention is not before Applicants' invention.

Withdrawal of the rejection under 35 U.S.C. § 102(e) is respectfully requested.

**The Rejection of Claims 1, 65, and 66 under 35 U.S.C. § 103(a)**

Claims 1-13 have been rejected under 35 U.S.C. § 103(a) as being obvious over Bosch for the reasons noted at pages 11-12 of the Office Action. Applicant respectfully traverses this rejection.

As provided in the Office Action and in MPEP § 706.02(I), this rejection may be overcome, in accordance with 35 U.S.C. § 103(c), by showing that, at the time the claimed invention was made, the subject matter of the reference and the claimed invention were owned by the same person or subject to an obligation of assignment to the same person. Specifically, under MPEP § 706.02(I)(2)(II), a statement to this effect by an attorney of record is sufficient to constitute the necessary showing. In this regard, Applicants' undersigned representative hereby represents the following:

**U.S. Application No. 10/072,600 and U.S. Patent No. 5,994,391 were, at the time of the invention of U.S. Application No. 10/072,600 was made, owned by G.D. Searle and Company, Skokie, Ill., USA.**

Withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.



CONCLUSION

Accordingly, in view of the above remarks, this application is believed to be in condition for allowance, and a written indication of the same is respectfully requested.

Respectfully submitted,

Date: September 4, 2003

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